

attached hereto. Under 37 C.F.R. §1.121(b)(iii), a "marked-up" version does not have to be supplied for an added paragraph as it is sufficient to state that a particular paragraph has been added. Applicant is adding an Abstract of the Disclosure. No new matter has been added within the meaning of 35 U.S.C. §132.

**In the Claims:**

Please amend the claim 42 as indicated in Appendices A and B attached hereto. Appendix A is a "marked-up" copy of amended claim 42 and Appendix B is a "clean" copy of amended claim 42. No new matter has been added within the meaning of 35 U.S.C. §132.

**REMARKS**

Claims 22-55 are currently pending in the present application. The claims and specification have been amended in the expectation that the amendments will place this application in condition for allowance. The amendments do not introduce new matter under the meaning of 35 U.S.C. §132. Accordingly, entry of the amendments is respectfully requested.

**1. Objection to the Specification**

The Official Action states that the Specification is objected to because the application does not contain an Abstract of the Disclosure. Applicant has amended the Specification to include an Abstract. The amendment to the Specification adding the Abstract is found in Appendix C attached hereto.

Accordingly, the Applicant respectfully requests the Examiner reconsider and withdraw the objection to the Specification.

**2. Rejection of Claim 42 under 35 U.S.C. §101**

The Official Action states that claim 42 is rejected under 35 U.S.C. §101 for the following reasons:

Claim 42 is rejected under 35 U.S.C. §101 because the claimed invention is directed to "Use of the active ingredient matrix" which is non-statutory subject matter.

Applicant has amended claim 42 to comply with proper U.S. patent practice; thus, removing the present ground for rejection. Applicant notes that the amendment of claim 42 did not narrow the scope of the claim.

Accordingly, the Application respectfully requests the Examiner reconsider and withdraw the rejection of claim 42 under 35 U.S.C. §101.

**3. Rejection of Claims 22-55 under  
35 U.S.C. §112, second paragraph**

The Official Action states that claims 1-55 are rejected under 35 U.S.C. §112, second paragraph, for the following reasons:

Claims 1-55 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1-55, the words "active ingredient" is indefinite because the activity has not been specified.

Applicant notes that claims 22-55 are currently pending in the application. The Official Action also notes that claims 22-55 are pending in the application. Thus, Applicant believes that the Examiner intended to reject only the pending claims 22-55.

Applicant respectfully traverses the rejection of claims 22-55 under 35 U.S.C. §112, second paragraph. The essential inquiry

pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A) the content of the particular application disclosure; (B) the teachings of the prior art; and (C) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

In reviewing a claim for compliance with 35 U.S.C. §112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. §112, second paragraph. See, e.g., *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000).

In the present application, the expression "active ingredient" is used as a literal translation of the German term "Wirkstoff", which is meant to describe a chemical substance exhibiting a specific action or effect. In the context of the present invention, "active ingredient" is a drug, a medicament, a pharmaceutical or a diagnostic. See paragraphs 14, 19, 20, 22, 40-44 of the instant Specification. Thus, the content of the instant application distinctly defines "active ingredient".

In addition, as used in the claims and specification, the word

"active" is an adjective denoting a quality of the "ingredient". Further, the phrase "active ingredient" is well known in the art and its use in the claims is consistent with its meaning in the art. Thus, there is no activity to be specified, As stated above, "active ingredient" is a drug, a medicament, a pharmaceutical or a diagnostic as defined in paragraphs 14, 19, 20, 22, 40-44 of the instant Specification.

Accordingly, the Applicant respectfully requests the Examiner reconsider and withdraw the rejection of claim 22-55 under 35 U.S.C. §112, second paragraph.

**CONCLUSION**

Claims 22-55 are currently pending in the present application. Applicant respectfully requests the Examiner to reconsider and withdraw the outstanding rejections and objections and allow all pending claims.

The Examiner is welcomed to telephone the undersigned attorney if she has any questions or comments.

Respectfully submitted,

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Attorney Docket No. 24689

BOX 1000

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RECEIVED

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Edmund SCHOLL

Serial No.: 09/857,554

Group Art Unit: 1615

Date Filed: July 23, 2001

Examiner: Sharon Howard

For: **ACTIVE INGREDIENT MATRIX IN THE FORM OF A BIOLOGICALLY RESORBABLE POROUS NON-WOVEN, METHOD FOR THE PRODUCTION AND USE THEREOF**

**APPENDIX A - "Marked-up" copy of Claim Amendments**

Please amend the claims as indicated below. Applicant herewith submits the following "marked-up" copy of the amended claims under 37 C.F.R. §1.121(c)(i). No new matter has been added under the meaning of 35 U.S.C. §132.

42. (Amended) A method of treatment comprising the steps of:  
[Use of the] administering the active ingredient matrix according to claim 22, wherein said active ingredient matrix is [as] an implantable and completely resorbable depot for active ingredients with a retarded active ingredient delivery.



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APPENDIX B - "Clean" copy of Amended Claims

Please amend the claims as indicated below. Applicant herewith submits the following "clean" copy of the amended claims under 37 C.F.R. §1.121(c)(i). No new matter has been added under the meaning of 35 U.S.C. §132.

42. (Amended) A method of treatment comprising the steps of:  
administering the active ingredient matrix according to claim 22,  
wherein said active ingredient matrix is an implantable and  
completely resorbable depot for active ingredients with a retarded  
active ingredient delivery.



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For: **ACTIVE INGREDIENT MATRIX IN THE FORM OF A BIOLOGICALLY RESORBABLE POROUS NON-WOVEN, METHOD FOR THE PRODUCTION AND USE THEREOF**

APPENDIX C - "Clean" copy of Amendment to Specification

Please amend the Specification by adding the following Abstract of the Disclosure. Under 37 C.F.R. §1.121(b)(iii), a marked up version does not have to be supplied for an added paragraph as it is sufficient to state that a particular paragraph has been added. No new matter has been added under the meaning of 35 U.S.C. §132.

ABSTRACT

The present invention relates to an active ingredient matrix in the form of a biologically resorbable porous non-woven made of collagen fibrils in a dry frozen state with delayed release of said active ingredients. The matrix contains at least one homogeneously divided active ingredient that has low solubility in water, body fluids and other physiological mediums. A low soluble active ingredient, in a finely divided form, is added to a collagen suspension produced in a certain manner in order to produce the inventive active ingredient matrix.